§ 113.32 Detection of Brucella contamination.

The test for detection of Brucella contamination provided in this section shall be conducted when such a test is prescribed in an applicable Standard Requirement or in a filed Outline of Production for the product.

(a) One ml of the minced tissue used as the source of cells or 1 ml of the extract of the tissue prior to the addition of antibiotics, diluent and stabilizer, shall be inoculated onto each of three tryptose agar plates and incubated in a 10 percent CO_2 atmosphere at a temperature of 35–37 °C for at least 7 days.

(b) If colonies are identified as Brucella, the biological product is unsatisfactory.

(c) If colonies suspicious of Brucella are observed but cannot be identified as a Brucella species, either

(1) The biological product shall be regarded as unsatisfactory and destroyed; or

(2) Further subculture or other procedures shall be carried out until a positive identification can be made.

[38 FR 29888, Oct. 30, 1973]

§ 113.33 Mouse safety tests.

One of the mouse safety tests provided in this section shall be conducted when such test is prescribed in a Standard Requirement or in the filed Outline of Production for a biological product recommended for animals other than poultry: *Provided*, That if the inherent nature of one or more ingredients makes the biological product lethal or toxic for mice but not lethal or toxic for the animals for which it is recommended, the licensee shall demonstrate the safety of such product by an acceptable test written into such Outline of Production.

(a) Final container samples of completed product from live virus vaccines shall be tested for safety using young adult mice in accordance with the test provided in this paragraph.

(1) Vaccine, prepared for use as recommended on the label, shall be tested. Eight mice shall be inoculated intracerebrally with 0.03 ml and eight mice shall be inoculated intraperitoneally with 0.5 ml. Both groups shall be observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in two or more mice in either group during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur in two or more mice in either group, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

(b) Bulk or final container samples of completed product from liquid products, such as but not limited to antiserums and bacterins, shall be tested for safety in accordance with the test provided in this paragraph.

(1) Unless otherwise prescribed in the Standard Requirement or approved in a filed Outline of Production for the product, a 0.5 ml dose shall be injected intraperitoneally or subcutaneously into eight mice and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated: *Provided*, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

[38 FR 34727, Dec. 18, 1973, as amended at 39 FR 16857, May 10, 1974]

EFFECTIVE DATE NOTE: At 72 FR 72564, Dec. 21, 2007, §113.33 was amended by revising paragraphs (a)(1) and (a)(2), effective Jan. 22, 2008. For the convenience of the user, the revised text is set forth as follows:

§ 113.33 Mouse safety tests.

* * * * *

(a) * * *

(1) Vaccine prepared for use as recommended on the label shall be tested by inoculating eight mice intraperitoneally or subcutaneously with 0.5 mL (the inoculation volume may be divided among more than one injection site), and the animals observed for 7 days.

(2) If unfavorable reactions attributable to the product occur in any of the mice during